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IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA SECOND APPELLATE DISTRICT

DIVISION SEVEN

THOMAS K. MILLS,

Plaintiff and Appellant,

v.

JANSSEN PHARMACEUTICALS, INC.,

Defendant and Respondent.

B300508

(Los Angeles County Super. Ct. No. BC652652)

APPEAL from a judgment of the Superior Court of Los Angeles County, Daniel J. Buckley, Judge. Affirmed. Thomas K. Mills, in pro. per., for Plaintiff and Appellant. Faegre Drinker Biddle & Reath, Rodney M. Hudson, and William A. Hanssen, for Defendant and Respondent.

INTRODUCTION

Thomas K. Mills appeals from the judgment entered in his products liability action against Janssen Pharmaceuticals, Inc. after the trial court denied Mills's motion for summary judgment and granted Janssen's motion for summary judgment. Representing himself on appeal, as he did in the trial court, Mills contends the trial court erred in denying his motion and granting Janssen's. We affirm.

FACTUAL AND PROCEDURAL BACKGROUND

In March 2017 Mills filed this action for products liability, personal injury, and "intentional tort" against Janssen, which makes and markets the antipsychotic drug Risperdal, the brand name for risperidone, "an antipsychotic medication that was first approved by the FDA in 1993 for managing manifestations of psychotic disorders in adults." (*Risperdal & Invega Cases* (2020) 49 Cal.App.5th 942, 947.) Mills alleged the drug, which doctors prescribed him while he was incarcerated for periods in 2014 and 2016, caused him to develop gynecomastia. He alleged Janssen

Gynecomastia is "a condition characterized by the enlargement of male breast tissue." (Risperdal & Invega Cases, supra, 49 Cal.App.5th at p. 946.) "Risperidone elevates blood levels of prolactin, a hormone produced by the pituitary gland. Elevated levels of prolactin (hyperprolactinemia) are associated with gynecomastia." (Id. at p. 947, fn. omitted.) "Prolactin . . . is a protein that is best known for its role in enabling mammals, usually females, to produce milk." (W.C. v. Janssen Pharmaceuticals, Inc. (In re Risperdal Litig.) (Pa. Super.Ct. 2017) 174 A.3d 1110, 1121, fn. 6; see State ex rel. Wilson v.

knew gynecomastia was a common side effect of the drug but did not "place any warning about the side effect" on the product.

In January 2019 Mills filed a motion for summary judgment, which is not in the record. In June 2019 Janssen moved for summary judgment on the grounds, among others, that at all relevant times Risperdal's label disclosed the potential risk of gynecomastia and that Mills could not establish a different warning would have altered his treating physicians' decisions to prescribe Risperdal.

In support of its motion Janssen submitted evidence that during the relevant period the package insert for Risperdal included, among its "Warnings and Precautions," statements that Risperdal "elevates prolactin levels and the elevation persists during chronic administration," that Risperdal "is associated with higher levels of prolactin elevation than other antipsychotic agents," and that gynecomastia had "been reported in patients receiving prolactin-elevating compounds." In addition, in an "Adverse Reactions" section, under the subheading "Other Adverse Reactions Observed During the Clinical Trial Evaluation of Risperidone," the insert named gynecomastia and hyperprolactinemia (i.e., elevated levels of prolactin) in a list of disorders that followed these statements: "The following adverse reactions occurred in < 1% of the adult patients and in < 5% of the pediatric patients treated with RISPERDAL® in the above double-blind, placebo-controlled clinical trial data sets. In addition, the following also includes adverse reactions reported in

Ortho-McNeil-Janssen Pharmaceuticals, Inc. (2015) 414 S.C. 33, 51, fn. 7 ["Prolactin is a hormone that causes breasts to grow and produce milk"].)

RISPERDAL®-treated patients who participated in other studies, including double-blind, active-controlled and open-label studies in schizophrenia and bipolar mania studies in pediatric patients with psychiatric disorders other than schizophrenia, bipolar mania, or autistic disorder, and studies in elderly patients with dementia."²

Janssen also submitted deposition testimony from the three doctors who prescribed Risperdal for Mills in 2014 and 2016. Dr. Maya Kumar, who in 2014 diagnosed Mills with schizophrenic disorder bipolar type and prescribed Risperdal for a time to help treat it, stated in her deposition that when she prescribed Mills the drug she knew from its package insert and other sources about the risk of elevated prolactin levels and gynecomastia. She stated she considered these risks when she prescribed Mills the drug, decided the drug's benefit to him outweighed these risks, and although aware he shortly afterward claimed he developed gynecomastia, would make the same prescribing decision today. Dr. Arastou Aminzadeh, who prescribed Mills Risperdal in 2016 to help treat auditory hallucinations, and Dr. David Gellman, who renewed that prescription, made similar statements in their depositions.³

Janssen asserts, without citing the record, the "FDA approved these warnings in 2007 to conform to FDA's newly revised labeling requirements."

In his deposition Mills stated that, at the time Dr. Aminzadeh prescribed him Risperdal, Mills knew gynecomastia was a potential side effect of the drug, believed he had already experienced gynecomastia as a result of his earlier use of the drug, and agreed to take the drug because he believed the benefit outweighed the risk.

The trial court denied Mills's motion, ruling he did not establish he was entitled to judgment as a matter of law because he merely asserted the court should grant summary judgment in his favor based on "the evidence on file, and the videotaped deposition," and provided "no legal citation or argument from that evidence." The court granted Janssen's motion. The court stated that, "at their core, all of Plaintiff's claims arise under a failure to warn theory" and that a prescription drug manufacturer "discharges its duty to warn if it provides adequate warnings to the physician about any known or reasonably knowable risks, regardless of whether the warning reaches the patient." Citing Janssen's evidence that "Risperdal has been clearly labelled, since its FDA approval in 1993, to warn of the risks of gynecomastia associated with its use" and that, in response, Mills merely stated the warnings on the Risperdal label at the time he was prescribed the drug "were not adequate as a matter of law," the court ruled Mills failed to raise a triable issue of fact on whether Janssen breached its duty to warn. The court entered judgment in favor of Janssen, and Mills timely appealed.

DISCUSSION

A. Standard of Review

"Summary judgment is appropriate only 'where no triable issue of material fact exists and the moving party is entitled to judgment as a matter of law." (Regents of University of California v. Superior Court (2018) 4 Cal.5th 607, 618; see Valdez v. Seidner-Miller, Inc. (2019) 33 Cal.App.5th 600, 607.) "To meet its initial burden in moving for summary judgment, a defendant must present evidence that either 'conclusively negate[s] an element of [each of] the plaintiff's cause of action' or 'show[s] that

the plaintiff does not possess, and cannot reasonably obtain,' evidence necessary to establish at least one element of [each] cause of action." (Henderson v. Equilon Enterprises, LLC (2019) 40 Cal.App.5th 1111, 1116; see Aguilar v. Atlantic Richfield Co. (2001) 25 Cal.4th 826, 853-854.) "Once the defendant satisfies its initial burden, 'the burden shifts to the plaintiff . . . to show that a triable issue of one or more material facts exists as to the cause of action or a defense thereto." (Henderson, at p. 1116; see Aguilar, at p. 849.)

We review a trial court's ruling on a motion for summary judgment de novo. (Samara v. Matar (2018) 5 Cal.5th 322, 338.) We consider """" all the evidence set forth in the moving and opposing papers except that to which objections were made and sustained." [Citation.] We liberally construe the evidence in support of the party opposing summary judgment and resolve doubts concerning the evidence in favor of that party.""

(Hampton v. County of San Diego (2015) 62 Cal.4th 340, 347; see Hartford Casualty Ins. Co. v. Swift Distribution, Inc. (2014) 59 Cal.4th 277, 286.) "We affirm the trial court's decision if it is correct on any ground the parties had an adequate opportunity to address in the trial court, regardless of the reasons the trial court gave." (Wolf v. Weber (2020) 52 Cal.App.5th 406, 410.)

B. The Trial Court Did Not Err in Its Rulings on the Motions for Summary Judgment

Although Mills suggests "there is evidence in the record that supports [his] request for judgment," he offers no substantive argument on this point and cites no evidence. The record, moreover, does not include a copy of his motion for summary judgment or any evidence he may have submitted to support it. Mills has therefore failed to demonstrate any error by the trial court in denying his motion for summary judgment. (See *Abdulkadhim v. Wu* (2020) 53 Cal.App.5th 298, 301 [""[I]t is the appellant's responsibility to affirmatively demonstrate error and, therefore, to point out the triable issues the appellant claims are present by citation to the record and any supporting authority. In other words, review is limited to issues which have been adequately raised and briefed.""].)

Nor has he demonstrated the trial court erred in granting Janssen's motion for summary judgment. Mills does not dispute his causes of action rest on a failure-to-warn theory. (See Webb v. Special Electric Co., Inc. (2016) 63 Cal.4th 167, 179 ["A product can be defective in its manufacture or design, or because it fails to include a warning about known risks."].) "Generally speaking, manufacturers have a duty to warn consumers about the hazards inherent in their products." (Id. at p. 181.) In the case of prescription drugs, however, California has adopted the "learned intermediary doctrine," according to which "the duty to warn runs to the physician, not to the patient.' [Citation.] "[I]f adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed."" (Bigler-Engler v. Breg, Inc. (2017) 7 Cal.App.5th 276, 318; see Webb, at p. 187, fn. 10; Carlin v. Superior Court (1996) 13 Cal.4th 1104, 1116; Stevens v. Parke, Davis & Co. (1973) 9 Cal.3d 51, 65.) ""The rationale of the foregoing rule is: '(1) The doctor is intended to be an intervening party in the full sense of the word. Medical ethics as well as medical practice dictate independent judgment, unaffected by the manufacturer's control, on the part of the doctor. (2) Were the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the drug, he would have no way to evaluate it, and in his limited understanding he might actually object to the use of the drug, thereby jeopardizing his life. (3) It would be virtually impossible for a manufacturer to comply with the duty of direct warning, as there is no sure way to reach the patient.""" (*Bigler-Engler*, at p. 319.)

Janssen's evidence concerning the warnings that appeared in the Risperdal package insert and the statements by Mills's prescribing physicians showed that Janssen adequately warned those doctors of the risk of gynecomastia when prescribing Risperdal. And Mills does not dispute his doctors were adequately warned. Rather, he contends he raised a triable issue of material fact because "no warning was given to [him,] as a consumer" of the medicine. He argues (without citing to the record) that "[t]he consent form [he] was given to sign outlining the side effects of the medicine[] didn't mention anything about gynecomastia" and that "gynecomastia wasn't mentioned to [him] by any of the doctors." As stated, however, Janssen did not have a duty to make sure a warning of the risk of gynecomastia reached Mills through his doctors. (See Stevens v. Parke, Davis & Co., supra, 9 Cal.3d at p. 65; Bigler-Engler v. Breg, Inc., supra, 7 Cal.App.5th at p. 318.) Therefore, the trial court did not err in granting Janssen's motion for summary judgment.

DISPOSITION

The judgment is a	ffirmed. Th	ne parties ai	re to be	ear their
costs on appeal.				

SEGAL, Acting P. J.

We concur:

FEUER, J.

DILLON, J.*

^{*} Judge of the Los Angeles Superior Court, assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.